

OLC 75-2780

30 October 1975

MEMORANDUM FOR: Director

SUBJECT : Presidential Commission for the Protection
of Human Subjects Involving Biomedical and
Behavioral Research.

1. Attached for your consideration are the Pros and Cons of the subject legislation. My earlier memorandum covers the same ground and is attached as Tab D. While we may not wish to communicate your decision to the Senate Subcommittee at this time, we will need your decision in house so we can start preparing testimony for the 7th of November. Please verify your position by checking the appropriate boxes below.

DCI Membership.....Yes_____ No_____

CIA Acceptance of Commission Oversight..Yes_____ No_____

2. There are a few non-policy technical problems with the language of the Bill. These can be taken care of by negotiation with the Subcommittee.

3. Written views from the Office of Security, Office of Medical Services, Office of General Counsel, ORD, DDS&T, and Office of Scientific Intelligence are attached as Tab B. The views of the foregoing were expressed in Tab A. Tab C is a copy of the Bill.

George L. Cary
Legislative Counsel

Enclosures

Distribution:

Original - Director

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OLC 75-2780/a
30 October 1975

MEMORANDUM

SUBJECT: Presidential Commission for the Protection of
Human Subjects Involving Biomedical and Behavioral
Research

1. Subject bill, sponsored by Senators Kennedy, Javitz, and Schweiker, is designed to establish a permanent Commission to oversee human-use experimentation. The bill will double the size of the present temporary Commission by adding the Secretaries of Health, Education and Welfare, Defense, the DCI, the Administrator of the Veterans Administration, as well as four Representatives and four Senators. The purpose of adding Federal agencies, according to Senator Kennedy, is to provide a mechanism whereby Top Secret research can be reviewed by those members of the Commission who have such clearance. Finally, the bill requires Federal agencies to furnish information on such research and experimentation to the Commission on request. Therefore, the questions under consideration are whether the DCI should be a member of the Commission and whether the CIA, departing from past practices, should provide information on parts of its programs to the Commission.

2. The following treats the foregoing questions separately:

a. DCI membership on the Commission.

PRO: Membership would have the advantage of having the Agency views represented directly on the Commission and will allow the Agency to participate in the shaping of procedures.

PRO: In light of recent exposures of Agency improprieties in this area, it would be bad public relations to decline membership.

PRO: It would provide a forum for the exchange of information in this field. It would be a relatively cheap way to get a fix on the technology in this area as well as provide a channel to disseminate Agency information on foreign developments.

PRO: Membership will directly expose the Agency to contemporary public concern on the ethical and moral aspects of experimentation. It is another opportunity for the Agency to de-isolate itself.

* * * *

CON: Membership might lead to charges that the Agency was involved with domestic affairs.

CON: Since Agency programs are limited, the CIA has no contribution to make to the Commission's deliberations nor will it have any particular concerns about Commission pronouncements.

3. The provision of program information to the Commission is a departure from present practices. Although the Commission is a mixed bag, it is a Presidential Commission and as such, it will be difficult to evade its oversight. It is believed that the Agency can accept the additional oversight and live by the rules which may be forthcoming. There were some concerns expressed about security and the scope of the oversight.

Distribution:

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OLC:RC:cmw (typed 30 October 1975)



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DD/S&T# 4060-75/2

ORD 4300-75

6 OCT 1975

MEMORANDUM FOR: Executive Assistant/DD/S&T

SUBJECT : Hearing on Human Experimentation and Proposed
Legislation

1. The ORD recommendations for changes to the proposed Congressional Bill are as follows:

a. Page 2 in the sentence "Until such time as the President acts to appoint" -- insert the following:
members to the "Commission";

b. Page 4 following the statement "(including national security)" it is suggested that some modifier be included to indicate such revelations be made only in accordance with directives governing the protection of classified information.

c. Page 4--we suggest a change to the sentence "By majority decision of the Special Committee, such information shall be disclosed without regard to the sensitivity of such information to the full Commission upon a finding by the Special Committee that there is or will be an adverse impact upon the protection of human subjects of research." We suggest that this sentence be modified to direct that the Special Committee attempt to institute corrective action in any situation requiring the protection of human subjects of research. If those attempts should fail, the Special Committee could then bring this matter to the attention of the Full Commission in accordance with directives governing the protection of classified information. (For a similar matter on classification we call your attention to Employee Bulletin)

STATINTL

d. Page 5--it is believed that the phrase "institutionalized mentally inform" should read institutionalized mentally infirm.

SUBJECT: Hearing on Human Experimentation and Proposed Legislation

e. Page 6--in the statement "and employees and agents of the Central Intelligence Agency" we feel that it is important to insert the word "contractors" in lieu of "agents" since the CIA common useage for the title 'agent' would be a foreign national whose identity could not be revealed and it is felt that the intent of the Bill meant to reflect contractors.



Deputy Director
of
Research and Development

STATINTL

6 OCT 1975

DD/S&T-4060-75/1
6 October 1975

MEMORANDUM FOR: Office of Legislative Counsel
SUBJECT: Hearing on Human Experimentation and Proposed Legislation
REFERENCE: Letter from Senator Edward M. Kennedy dated 30 Sept 1975
(ER-75-8671/1) (OLC-75-2460)


1. The following comments are offered for use by the Director when testifying on the proposed legislation.

2. General - We recommend strongly that the DCI not be a member of the proposed commission. The CIA has no contribution to make to the deliberations of such a group nor particular concerns about its pronouncements--whatever they may be. At the same time, it appears that we can accept and live by any rules that may be forthcoming. If new concerns emerge with time, we can always seek any necessary relief. On these bases, we do not see why the DCI need be involved.

3. Specific - Sec. 481 (g) - The Special Commission decides whether or not classified material will be released to the full commission. However, nothing is then said as to how the commission will release the information to the public, and if it will first touch base with the originator.

Sec. 482 (a)(2) - We simply note that it seems odd to include "employees and agents of the Central Intelligence Agency" in the term "military personnel."

STATINTL


Sayre Stevens
Associate Deputy Director
for
Science and Technology

Approved For Release 2003/12/16 : CIA-RDP78-04163R000100100001-9

21 October 1975

STATINTL

MEMORANDUM FOR:

OLC

SUBJECT : Comments on Legislation to Establish a President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

1. The attached bill seems to be very poorly drafted.

a. The last sentence in section 481(a)(4) "[u]ntil such time as the President acts to appoint members of the National Commission for the Protection of Human Subjects of Biomedical or Behavioral Research are deemed members of the Commission as of the date of enactment of this act." carries unintelligibility to a new high. Hopefully it is a garble.

b. There seems to be a contradiction between section 481(a)(3) which states inter alia that the DCI shall be a member of the President's Commission for the protection of human subjects of biomedical and behavioral research and section 481(b) which states that the term of office of each member of the Board shall be four years. If "Board" is intended to be synonymous with "Commission" then, unless this bill is broadly hinting that the DCI be limited to a four year term, there would be obvious tension between subparagraphs (a) and (b) of section 481 in the fifth year. If "Board" is not synonymous with "Commission" then a definition would be useful.


c. Section 482(a)(2) defines "children," "prisoner," "institutionalized mentally infirm," and "military personnel." While it is most gratifying that CIA employees and agents are included in the latter rather than the former categories, a fifth category might be more appropriate.

2. On a more fundamental level, three objections may be levied against this bill. First, there is no need for CIA employees and agents to be singled out. Indeed, the legislative purposes would more faithfully be served if the bill were broadened so that in place of the present language in section 482(a)(2) that "[t]he Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, military personnel, and the institutionalized mentally

inform." [sic] The bill read "...children, prisoners, military personnel, civilian personnel, and" Certainly Congress cannot intend that the standards of informed consent, which would apply to members of the Armed Forces or the CIA, would not apply to agents of the FBI or DEA.

3. Second, there is no need for language which might further erode this Agency's abilities to carry out its functions. Thus, while it is objectionable that the Commission establish ethical principles and guidelines for the conduct of biomedical and behavioral research in order to protect human subjects, and legitimate that the Commission should be able to secure directly from any department or agency of the United States, information necessary to enable it to carry out it's duties [section 481(g)], it would be advisable to include language to the effect that "such information shall be limited to principles, procedures, and guidelines for selection and protection of human subjects and shall not include information on classified research or intelligence sources and methods." In this way the Commission would be able to "protect" human subjects and this Agency would be able to protect sensitive operations. This suggestion is made notwithstanding the fact that subsection (g) also provides that classified information shall be furnished to the "Special Committee" composed of four senators, four representatives, the Secretary of HEW, the Secretary of Defense, the Administrator of the Veteran's Administration, and the DCI because subsection (g) further states that "[b]y a majority decision of the Special Committee, such information shall be disclosed without regard to the sensitivity of such information to the full Commission upon a finding by the Special Committee that there is or will be an adverse impact upon the protection of human subjects of research." The automatic eight-to-four congressional majority could, in effect, override executive branch classification determinations and further erode the ability of the DCI to protect intelligence sources and methods.

4. Finally, it is necessary to question whether the DCI should be a member of the President's Commission for the protection of human subjects of biomedical and behavioral research. The DCI, as the senior intelligence officer of the United States Government, has at least four functions. These are: Providing foreign intelligence for U.S. policymakers; managing the Intelligence Community; protecting sources and methods; and managing intelligence relations with foreign governments. The function of this Commission is not sufficiently related to these DCI functions, and therefore, the DCI perhaps ought not serve on the Commission.


Office of General Counsel

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Approved For Release 2003/12/16 : CIA-RDP78-04163R000100100001-9

9 OCT 1975

MEMORANDUM FOR: Assistant Legislative Counsel

SUBJECT: Comments on Proposed Legislation
"President's Commission for the
Protection of Human Subjects of
Biomedical and Behavioral Research
Act of 1975"

1. The impact on the Agency of the proposed legislation should be considered in the following contexts:

a. The proposed existence of the Commission;

b. Membership on the Commission of the Director of the Central Intelligence Agency;

c. Power of the Commission to secure information;

d. Requirement to publish the recommendations of the Commission;

e. Power of the Commission to enforce its recommendations;

f. The transfer of the functions, powers and duties of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (88 Stat. 348-351) to the President's Commission;

g. The repeal of Part A of Title II of the National Research Act (42 USC 2891) and sections 211 and 213 of the National Research Act.

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SUBJECT: Comments on Proposed Legislation
"President's Commission for the
Protection of Human Subjects of
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2. The proposed objectives of the new Commission, in the light of the already extant extensive provisions for the protection of human subjects in medical research, strongly suggests that the proposed legislation is directed in part specifically toward the control of this subject in the CIA and military organizations and in certain subject areas such as psychosurgery and the use of prisoners that have been recently subject to congressional investigation. While employees and agents of the CIA are included as "military personnel", civilian employees of the Department of Defense, including employees of DIA, are not.

3. Membership on the Commission by the Director of the Central Intelligence Agency is surprising in view of the very small amount of human research carried out by the Agency in comparison to that carried out by other agencies and departments of the Government. His designation as Director of the CIA rather than Director of Central Intelligence implies that the CIA rather than the intelligence community is the focus of interest. Representation by the DCIA is good in the sense that we may have a voice in the procedures. This is important since potentially the Commission is powerful and uneducated in the unique and essential requirements of the intelligence profession.

4. The authority to be vested in the Commission to secure information without regard to security classification is of concern. Under specified circumstances such information may be divulged to the entire Commission. Such authority may affect the intelligence community and its ability to conduct intelligence activities. Measures to prevent unauthorized disclosure of classified information on sensitive intelligence activities should be provided for.

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SUBJECT: Comments on Proposed Legislation
"President's Commission for the
Protection of Human Subjects of
Biomedical and Behavioral Research
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5. The requirement to publish the recommendations of the Commission and under certain circumstances the response of the Agency in the Federal Register could also present a serious security problem. An alternative mechanism should be sought (see also 4. above).

6. The power of the Commission to enforce its recommendations indirectly will be very great indeed. Any action by the Agency contrary to the recommendations of the Commission will be subject to litigation.

7. The transfer of the functions, powers and duties of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to the President's Commission presumably invests the President's Commission with additional functions, powers and duties that are not described in the proposed legislation. Also, the repeal of certain specified portions of the National Research Act is noted but not described in the proposed legislation.

8. The proposed legislation was obviously designed to achieve several goals and may not have been designed optimally to achieve any one goal. The specific effect with which we are concerned is the formulation of proposed legislation for the protection of human subjects of biomedical and behavioral research carried out by or under the sponsorship of the CIA. In formulating such proposed legislation due consideration must be given to:

- a. the special requirements of the intelligence profession;
- b. the special requirements of responsiveness and accountability to the President and to the Legislative Branch in our Democracy;
- c. the clear distinction between research and intelligence operations (analogous in some respects to the distinction between medical

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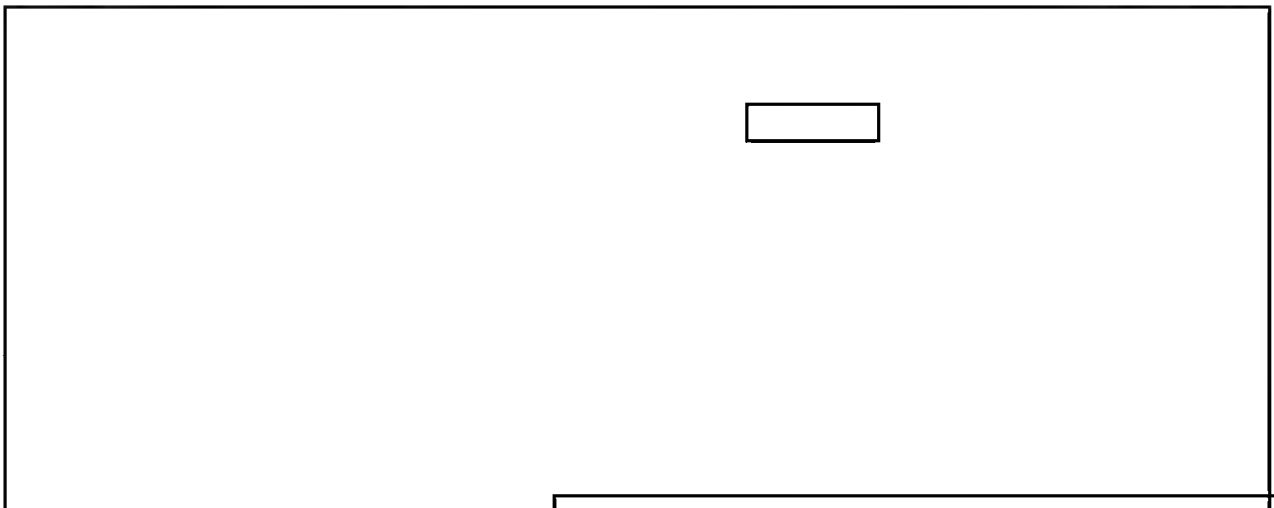
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SUBJECT: Comments on Proposed Legislation
"President's Commission for the
Protection of Human Subjects of
Biomedical and Behavioral Research
Act of 1975"

research and the practice of medicine alluded
to in the above proposed legislation; and

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d. the special requirement for secrecy
in the intelligence profession.



Acting Director
Scientific Intelligence

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10 OCT 1975

STATINTL

MEMORANDUM FOR:

Office of Legislative Counsel

SUBJECT : Proposed Senate Bill by Senator Kennedy
on the Protection of Human Subjects

REFERENCE : OLC 75-2460

1. The following comments which represent the views of the Office of Medical Services are forwarded for your consideration in the hope that they will provide constructive suggestions. At the outset I wish to emphasize that I applaud the general intent of Senator Kennedy's proposed Bill. Specifically, Sections 482 and 483 are matters of deep concern not only to health professionals but to the public in general. The legal, ethical and professional aspects of human experimentation are currently ranked among the most pressing problems in our society and is being addressed by a number of the most prestigious organizations and individuals concerned with these problems. The Office of Medical Services would certainly welcome and comply with established guidelines to the extent that they can be defined in a meaningful way.

2. Whether a Presidential Commission can add further focus and attention on the problem is hard to judge. If the sole purpose of the Bill is to assure compliance by the Central Intelligence Agency then it would appear to me that there is probably a simpler way to achieve that goal through existing Executive or Congressional direction.

3. If it is deemed advisable to establish a Presidential Commission then I would like to raise certain questions about the Bill as follows:

a. It strikes me that it might be inappropriate to include the Director of Central Intelligence as a

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SUBJECT: Proposed Senate Bill by Senator Kennedy on the
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member of the Commission as it would probably lead to charges that the Agency is involving itself in domestic matters. This must be weighed against the advantages of having the Agency's views represented directly on the Commission.

b. I have doubts as to whether a Commission of this size meeting periodically would be able to address in any detail all of the various aspects of human experimentation in depth unless it had a very substantial full-time staff. It has been our experience that policing the compliance of contractors, be they government or private, can be done quite effectively by our own staff given the appropriate guidelines.

c. Section 481 (2)(g) deals with the question of providing National Security Information to the full Commission and in some cases disclosure. This area should be examined most carefully since our experience resulting from the Katzenbach Report showed that some institutions were unwilling to undertake well-controlled and unclassified research if their institution would be openly identified with the Central Intelligence Agency. It is likely that outstanding research institutions would be even more reluctant to provide consultation and support in today's climate with the net effect that CIA will find it increasingly difficult to engage the services of organizations committed to the standards intended by Senator Kennedy.

4. I note that the proposed Bill recommends that the Commission investigate the use of psychosurgery but excludes electric shock treatment and other forms of brain surgery. I suspect that I share the same concerns about psychosurgery but question whether the Bill should proscribe a specific area of investigation and exclude other forms of therapy which are currently under review by health professionals.

5. I am unable to comment on whether a Presidential

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Protection of Human Subjects

Commission would provide benefits and direction beyond
those already incorporated under the National Research
Act but assume that this will be spelled out in some
detail.

STATINTL



.D.

M.D.

Deputy Director of Medical Services

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21 OCT 1975

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MEMORANDUM FOR: Legislative Counsel

ATTENTION :

THROUGH : Deputy Director for Administration

SUBJECT : Senate Bill to amend the Public Health Service Act to establish a President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

REFERENCE : OLC request for comments on subject bill, dated 2 October 1975 (OLC 75-2460)

1. Pursuant to the referenced request, the Office of Security has reviewed the subject bill proposed by the Subcommittee on Health. The following comments are forwarded for your consideration.

2. Sections 481(g) and 482(a)(1)(C) provide the Commission with the authority to review all biomedical and behavioral research on human subjects conducted by and through federal agencies and to directly secure from any agency information necessary to enable the Commission to carry out its duties. Should the secured information be classified, it would be received by and limited to the Commission's Special Classified Information Committee. However, if this Committee, during its consideration of such classified information, found that there is or would be an adverse impact upon the protection of human subjects of research, it must disclose the information to the full Commission without regard to the information's sensitivity.

3. Although the above requirements have little effect upon Office of Security programs, they do provoke security interest relative to protecting Agency classified information

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and intelligence sources and methods, should such Agency material be directed to the Commission. Thus, physical security procedures planned by the Commission along with clearability requirements for Commission members and associated staff personnel are security areas which need clarification.

4. Section 482(a)(2) identifies individuals who appear to be unable to protect their own rights such as children, prisoners and the mentally infirm. The inclusion of current and former military personnel with these types of individuals seem to be questionable. Further, to define CIA employees and agents as military personnel to the exclusion of civilian employees for the Department of Defense and other federal agencies is somewhat unclear.

5. Finally, Section 484(b) provides that any agency receiving Commission recommendations must publish such recommendations in the Federal Register and provide an opportunity for interested persons to submit written data, views and arguments with respect to such recommendations. Should the agency determine that the Commission's recommendations are not appropriate, the agency must publish in the Federal Register its determination together with an adequate statement of the reasons for it. This Section does not provide for exempting classified information from the publishing requirement.

6. In view of the above, it is recommended that the Office of Legislative Counsel request the Senate Subcommittee preparing the bill to consider these security issues in order to ensure that classified information is appropriately protected against unauthorized disclosure.

STATINTL


Robert W. Gambino
Director of Security

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and accounting procedures and limitations on expenditures and borrowings which the State may require, such State shall—

(1) have its entitlement under the State and Local Fiscal Assistance Act of 1972, or other comparable general purpose financial assistance from the Federal Government, as determined by the Secretary withheld until such time as the Board is satisfied and that such State is taking all practicable steps to assure that such obligations and undertakings as are set forth in the plan required by subsection (c) of this section are being met; or

(2) shall be assessed a civil penalty equal to such sums to which the State was entitled under the State and Local Fiscal Assistance Act of 1972 for the fiscal years June 30, 1973, June 30, 1974, and June 30, 1975.

(g) The Secretary shall consult, as necessary, with any State or general local government which has received assistance under this Act concerning any matter which may bear upon the ability of the unit of government to repay the obligation within the time fixed therefor and reasonable protection to the United States.

DESCRIPTION OF BILL

Title: Emergency Intergovernmental Assistance Act of 1975.

General Description: The bill establishes an Emergency Intergovernmental Assistance Board composed of five members—the Secretary of the Treasury, the Secretary of HUD, and three members with outstanding private experience appointed by the President with the advice and consent of the Senate. The Board will determine, by majority vote, whether jurisdictions are eligible for assistance provided under this Act. The Board will have not to exceed ten days from the date of application in which to make this decision. If the Board votes in favor of assistance, this recommendation is then passed on to the Secretary of the Treasury who shall provide assistance by guaranteeing a taxable bond issued by the eligible state or local government. The Secretary has no discretion as to whether to provide assistance once the Board has voted favorably.

Eligible Governments: Any state or general purpose unit of local government will be eligible for this assistance. In the case of a local government, the state will also have to participate in the application (see Other Requirements). In order to be eligible for assistance, the state or local government must have failed in a bonafide attempt to obtain private financing. In addition, in the case of a local government, the state would have to show that it had provided as much assistance to the local government as is feasible without jeopardizing the State's own credit worthiness.

Eligible Securities: Any taxable bond guaranteed by the Federal Government would have to be backed by the full faith and credit of the issuing government.

Maturities of Guarantees: The guarantees could be offered on securities with maturities of up to ten years.

Interest Rate, Fees and Charges: The guaranteed taxable bonds will have their interest rate set by the market, but will also require a service fee of up to one percent.

Other Requirements: Financial Plan. As a prerequisite for the provision of assistance under this Act, each eligible state or local government must submit to the Board and the Secretary of the Treasury a three-year plan detailing the applicant's projected revenues, expenditures, scheduled borrowings, debt service costs and other information that the Board may require. In the case of a local government, the State would be required (through the endorsement of the Governor) to sign onto and participate in the enforcement of the plan. The plan must also contain (a) specific proposals to assure the achievement of a

budget within two years of receipt of the application for the retirement of the applicant's non-current short-term debt and (c) specific assurances that the State will permit the applying local government to use any lawful revenue raising mechanisms that may be necessary to avert default on the guaranteed obligations.

No expenditures or borrowings would be permitted that were not specifically included in the plan.

The Board can approve by majority vote any amendments to the plan.

Any State that failed to enforce a plan that it had endorsed would have its revenue sharing payment (or other general purpose financial assistance) withheld until it was once again in compliance with the requirements of the Act.

By Mr. KENNEDY (for himself, Mr. SCHWEIKER, and Mr. JAVITS):
S. 2515. A bill to amend the Public Health Service Act to establish the President's Commission for the protection of human subjects involved in biomedical and behavioral research, and for other purposes. Referred to the Committee on Labor and Public Welfare.

Mr. KENNEDY. Mr. President, I rise on behalf of myself and Senators JAVITS and SCHWEIKER to introduce the President's Commission for the protection of Human Subjects of Biomedical and Behavioral Research Act of 1975, which reestablishes the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as a Presidential Commission, broadens its jurisdiction, and expands the composition of its membership.

Mr. President, this Nation was shocked several years ago by the revelations of unethical research and unethical medical practice carried out in programs sponsored by Department of Health, Education, and Welfare funds. In Tuskegee, Ala., black men were enrolled in a syphilis study and were denied treatment for this dread disease for over 30 years, long after the time that syphilis became an easily treated disease. In Montgomery, Ala., Alice and Minnie Relf, two teenage girls, one of whom was retarded, were sterilized without their parent's knowledge or consent. In Mississippi, experimental psychosurgical techniques were carried out without proper experimental designs and without fully informed consent.

During the Health Subcommittee's investigations of these matters, Dr. Bernard Barber, the distinguished sociologist from Barnard University in New York City, presented the results of his National Survey of Biomedical research programs which raised profound ethical questions about all kinds of research in all kinds of settings. The committee was shocked to see the extent of the use of approved drugs for unapproved purposes. DES was widely used as a morning-after contraceptive across the Nation, especially on college campuses, without proper informed consent. In fact, it became clear that in the United States, in spite of a strict drug regulatory system, drugs are frequently used for new purposes. Sometimes, these purposes turn out to be legitimate and approval subsequently follows. Often times, these uses are not

because except after they are injured. In the State of Tennessee, the experimental drug, depo-provera, was in widespread and common use in the family planning clinics throughout that State as an injectable contraceptive. No informed consent accompanied the use of this experimental drug. Indeed, the drug was used at the Arlington School and Hospital for the Mentally Retarded. Again, there was no informed consent.

The subcommittee also heard of the use of medical devices, which were developed in isolation, without careful scientific scrutiny, and which did grievous harm to many patients.

The common thread of all of these stories was the absence of informed consent, the absence of adequate protection for the patient. In all cases, the doctor or the researcher was able to operate without the checks and balances which have since been accepted as an integral part of the biomedical and behavioral research process.

The Congress responded to these outrageous abuses by enacting the National Research Act of 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Because the hearings had focused on abuses in the Department of Health, Education, and Welfare, and because it was believed that most of the violations occurred in programs under the purview of that agency, and because focusing on that agency alone was in itself a mammoth job, the Commission's jurisdiction was limited to the programs of HEW. As structured, the Commission which has been in existence for 10 months, reviews the policies for the protection of human subjects in HEW. It specifically was charged with focusing on fetal research, psychosurgery, research on children, prisoners, and the mentally retarded, as well as the overall protection system for human subjects. It is charged with making recommendations in all of these areas. The Secretary of HEW, though not bound to follow the recommendations, must, if he chooses to disagree with the Commission, publish the reasons for his disagreement in the Federal Register so that all interested parties, including the Congress, will know and will have an opportunity to take corrective action, if warranted. It also assures that the entire process will be a public and open one.

In establishing this Commission, the Congress clearly stated that the highly emotional issues involved in human experimentation required careful, scholarly study by a group of persons with a wide range of backgrounds. It was hoped that this interdisciplinary approach would focus the best minds in the country on the ethical dilemmas raised by human experimentation. I believe the first report of that Commission, the report to the Secretary on fetal research, illustrates the value and importance of the National Commission.

Mr. President, one of the responsibilities for the National Commission is to recommend to the Congress a mechanism for the expansion of its jurisdiction so as to cover all programs of biomedical and behavioral research which are conducted with Federal funds regard-

less of which Federal agency administrators those grants or contracts.

I believe, however, that it is no longer necessary or desirable to wait for the Commission to make that recommendation. The revelations of the past months concerning biomedical and behavioral research abuses in the Department of Defense and the CIA underscore the urgent need to expand the National Commission's jurisdiction and to expand it now. The abuses that have been uncovered in the research programs of the Defense Department and the CIA are of a magnitude every bit as frightening, every bit as outrageous and every bit as incompatible with the spirit of biomedical and behavioral research, and warrant immediate action.

The full extent of abuses is still not known. The Defense Department itself is unable to recount to the Health Subcommittee the full extent of biomedical and research activities or the conditions under which they are carried out. We do know that research involving LSD was carried out on human subjects without their knowledge or consent. We do know that research was carried out without proper medical supervision. We do know that treatment for unexpected side effects was delayed because of the inadequate medical care. We do know that at least one death and several suicide attempts resulted from these research efforts. We do know that the LSD research experiments continued up until 1973, long after the initial hearings on human experimentation were being done by the Senate and long after the standards for the conduct of biomedical and behavioral research had altered in this country.

We also learned in these hearings that the unethical research carried out by the Defense Department usually bore a secret label. Although the Defense Department had policies enunciating high principles for the ethical conduct of biomedical and behavioral research, the abuses uncovered at the Senate hearings involved a complete departure from these principles. Experimentation boards designed to review all human subject research were bypassed by the Edgewood Arsenal in Maryland. The director of that arsenal claims never to have been instructed to send his protocols there. He also claims to have obtained informed consent from all of his patients, yet was able to furnish only a standard informed consent sheet—the same sheet was used for every single research project carried out there.

Mr. President, the measure that I am introducing on behalf of myself and Senators Javirs and Schweiker takes the long-needed step of assuring the people of this country that all research, no matter where it is conducted or by whom, if it is funded with Government money, will come under the purview of the President's commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission will have its membership expanded to include as nonvoting members, the secretaries of HEW and the Department of Defense, the director of the CIA, and the Administrator of the Veterans' Administration, as well as four Members from the House of Representa-

tives and four Members from the Congress. The President of the Commission will be expected to serve out the remainder of their terms. The purpose for the expansion of the membership is both to upgrade the importance and impact of the work of the Commission, as well as to provide a mechanism whereby top secret research can be reviewed by those members of the Commission who have such clearance.

Mr. President, this Nation has always had a biomedical and behavioral research program second to none. The Commission gives this Nation a policy for the protection of human subjects of research second to none. It makes no sense to limit its jurisdiction. It makes no sense to have the Commission dissolved in 2 years to be replaced by a permanent advisory committee with the same responsibilities. This Nation needs a permanent commission. This Nation needs a permanent commission with the authority to standardize all biomedical and behavioral research conducted under Government funds. This legislation accomplishes this goal.

Mr. President, hearings will be held on this legislation next month. Any interested parties should contact Dr. Larry Horowitz at the Health Subcommittee Office, room 4228, New Senate Office Building, as soon as possible.

Mr. President, I ask unanimous consent that the text of this legislation be printed in the Record.

There being no objection, the bill was ordered to be printed in the Record, as follows:

S. 2515

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Act of 1975".

AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT

Sec. 2. Title IV of the Public Health Service Act is amended by inserting the following new part at the end thereof:

"PART J—PROTECTION OF HUMAN SUBJECTS
"ESTABLISHMENT OF COMMISSION

"Sec. 481. (a) There is established a Commission to be known as the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter in this title referred to as the "Commission"). The Commission shall be composed of—

"(1) four members of the Senate appointed by the President of the Senate; and

"(2) four members of the House of Representatives appointed by the Speaker of the House of Representatives; and

"(3) the Secretary of the Department of Health, Education and Welfare, the Secretary of Defense, the Director of the Central Intelligence Agency, and the Administrator of the Veterans' Administration; and

"(4) eleven members appointed by the President of the United States with the advice and consent of the Senate.

"The President shall select members of the Commission under paragraph (4) from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but

five (and not more than five) of the members shall be individuals who have been engaged in biomedical or behavioral research involving human subjects. Until such time as the President acts to appoint members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research are deemed members of the Commission as of the date of enactment of this Act.

"(b) The term of office of each member of the Board shall be four years; except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; (2) the terms of office of members first taking office shall begin on the date of appointment and shall expire, as designated at the time of their appointment, four at the end of one year, four at the end of two years, and three at the end of four years; and (3) a member whose term has expired may serve until his successor has qualified.

"(c) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings. Those members appointed under paragraphs (1), (2), and (3) of Section 481

(a) shall be non-voting members and shall not be considered in constituting a quorum.

"(d) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive \$100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel subsistence and other necessary expenses incurred in the performance of such duties.

"(e) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

"(f) (1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

"(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of \$100 per diem, including travel time, while away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

"(g) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties. Upon request of the Chairman of the Commission, each and every agency or department of the United States shall furnish all information requested by the Commission which is necessary to enable it to carry out its duties. If any information so requested has been deemed to be classified for any purpose (including national security) by such agency or department, such information shall be furnished to the Special Classified Information Committee of the Commission (here-

in after in this section referred to as the "Special Committee"), which shall be composed of those members of the Senate who are appointed under paragraphs (1), (2), and (3) of section 481(a). Eight members of the Special Committee shall constitute a quorum, but a lesser number may conduct hearings. By a majority decision of the Special Committee, such information shall be disclosed without regard to the sensitivity of such information to the full Commission upon a finding by the Special Committee that there is or will be an adverse impact upon the protection of human subjects of research.

"COMMISSION DUTIES

"Sec. 482. (a) The Commission shall carry out the following:

"(1) (A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the appropriate agency or department for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the appropriate agency or department, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research.

"(B) In carrying out subparagraph (A), the Commission shall consider at least the following:

"(i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.

"(ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.

"(iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.

"(iv) The nature and definition of informed consent in various research settings.

"(v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards established in accordance with section 474 of this Act and appropriate enforcement mechanisms for carrying out their decisions.

"(C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by the Secretary of HEW and shall review and suggest the ethical, social and legal implications of all biomedical and behavioral research on human subjects conducted by and through any Federal agency (including contractors) for which any Federal funds are to be appropriated.

"(2) The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, military personnel, and the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary and involving children, prisoners, military personnel, and the institutionalized mentally infirm to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the

competence and the freedom of the persons to make a choice for or against involvement in such research. The Commission shall investigate and study, the Commission shall make such recommendations to any department or agency of the United States as it determines appropriate to assure that biomedical and behavioral research conducted by or supported under the appropriate department or agency of the United States meets the requirements respecting informed consent identified by the Commission. For purposes of this paragraph, the term 'children' means individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the research is to be conducted; the term 'prisoner' means individuals involuntarily confined in correctional institutions or facilities (as defined in section 601 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3701)); and the term 'institutionalized mentally infirm' includes individuals who are mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution; the term 'military personnel' means individuals who are active and inactive members of the U.S. Armed Forces, veterans of the U.S. Armed Forces, and employees and agents of the Central Intelligence Agency.

"(3) The Commission shall conduct an investigation and study of the use of psychosurgery in the United States during the five-year period ending December 31, 1972. The Commission shall determine the appropriateness of its use, evaluate the need for it, and recommend to the Secretary policies defining the circumstances (if any) under which its use may be appropriate. For purposes of this paragraph, the term "psychosurgery" means brain surgery on (1) normal brain tissue of an individual who does not suffer from any physical disease for the purpose of changing or controlling the behavior or emotions of such individual, or (2) diseased brain tissue of an individual, if the sole object of the performance of such surgery is to, control change, or affect any behavioral or emotional disturbance of such individual. Such term does not include brain surgery designed to cure or ameliorate the effects of epilepsy and electric shock treatments.

"SPECIAL STUDY

"Sec. 483. The Commission shall undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology. Such study shall include—

"(1) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;

"(2) an analysis and evaluation of the implications of such advances, both for individuals and for society;

"(3) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;

"(4) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and

"(5) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advances in biomedical and behavioral research and technology and public attitudes toward such advances.

"ADMINISTRATIVE PROVISIONS

"Sec. 484. (a) The Commission may for the purpose of carrying out its duties hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission deems advisable.

"(b) Within sixty days of the receipt of any recommendation made by the Commission under section 482, the appropriate de-

partment or agency of the United States shall publish it in the Federal Register and proposed interested persons to submit written data, views, and arguments with respect to such recommendation. The appropriate department or agency of the United States shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by it, and (2) if it determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for its determination. If the appropriate department or agency of the United States determines that administrative action recommended by the Commission should be undertaken by it, it shall undertake such action as expeditiously as is feasible.

"AUTHORITY TO CONTRACT

"Sec. 485. The Commission may contract for the study and design of mechanisms to be included in such recommendations.

"TRANSFER OF FUNCTIONS

"Sec. 486. The functions, powers, and duties of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (88 Stat. 348-351) shall be transferred to the Commission."

MISCELLANEOUS

"Sec. 3. (a) Part A of title II of the National Research Act (42 U.S.C. 2801) is repealed.

(b) Sections 211 and 213 of the National Research Act are repealed.

Mr. SCHWEIKER. Mr. President, the accounts of unsupervised experiments on humans in military and CIA drug research—revealed during recent hearings before the Subcommittee on Health, of which I am ranking minority member—are indicative of the need for the bill Senators KENNEDY, JAVITS, and I have introduced today.

During the hearings we learned of secret experiments with LSD and other hallucinogenic drugs conducted on military personnel with virtually no medical supervision or followup, and little adherence to established ethical principles.

In order to provide a responsible body to review the issues presented to the committee, this bill creates the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and transfers the functions, powers, and duties of the National Committee for the Protection of Human Subjects of Biomedical and Behavioral Research to the new Commission. The Commission shall be composed of the Secretary of Health, Education and Welfare; the Secretary of Defense; the Director of the Central Intelligence Agency; the Director of the Veterans' Administration, 8 Members of Congress, equally divided between the House and Senate, appointed by the Speaker of the House and the President of the Senate, respectively; and 11 members from the public appointed by the President with the advice and consent of the Senate. The Commission shall be responsible for the review of all federally funded biomedical and behavioral research programs.

The bill recognizes that it may be necessary for reasons of national security to authorize special consideration for research involving military personnel.

MEMORANDUM FOR: Director of Central Intelligence

SUBJECT: Agency Comments on Proposed Bill
to Establish Commission on
Human Experimentation

1. This memorandum sets forth a recommendation contained in paragraph 6.

2. The Kennedy Subcommittee, in connection with its hearings on human experimentation, has requested comments from the Agency on proposed legislation to establish a President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, composed of selected Members of Congress, Secretaries of HEW and Defense, the Administrator of the Veterans Administration, the Director of CIA (all nonvoting) and Presidential appointees from the private sector would: conduct a comprehensive investigation to identify ethical principles underlying the conduct of biomedical and behavioral research; and make recommendations to agencies and departments. Employees and agents of the Central Intelligence Agency are specifically within the jurisdiction of the Commission.

3. The Commission can request any information from any Government agency needed to carry out its responsibilities. All classified information would be sent to a "Special Committee" of the Commission of which the DCI would be a member. The Special Committee, by majority vote, must provide any classified information to the full Commission if it finds that there will be an adverse impact on human subjects. There is no provision in the legislation as to the degree of protection to be provided classified information by the Special Committee. Nor is there any provision as to what disposition the Commission may make of the information. Presumably, the Commission could make it public.

4. It is the consensus of Agency components that the Director of CIA should not serve as a member of the Commission since the Agency has very little current research in these areas and none which can be considered as affecting the health of the subjects involved. Further, with such limited activities, it was not considered appropriate or advisable for the Director of Central Intelligence to participate in the formulation of guidelines for all of Government. It was clearly acknowledged, however, that the Agency would adhere strictly to any guidelines issued by the Commission and would provide information on our programs to the Commission consistent with the protection of intelligence sources and methods.

5. There is an opposite view for your consideration as to whether the DCI should be a member of the Commission. Though our programs in the past were not large, they were extensive and included many facets of controlling human behavior. There admittedly were abuses. It would be difficult to refuse to participate in the wake of the charges. We should be part of the mainstream in this important area and not isolate ourselves. The Commission would become educated on the unique and essential requirements of the intelligence profession. Further, membership would allow for the free flow of information on human experimentation and would enhance the Agency's knowledge and collection of foreign intelligence developments in this area.

6. While there appears to be little substantive basis for including the Director of Central Intelligence in the membership of the Commission, there may well be some advantages from a tactical and public relations point of view. There is no question but that we will be engaging in this kind of activity to a limited degree in the future, and it may be in our best interest to have the Director on the Commission for the reasons stated in paragraph 5. Since you or an Agency representative will possibly be asked to testify on this proposal, I suggest that we not make a decision against your participation in the Commission in advance of the hearings. In the meantime, we will consult with the White House regarding both the substance of the legislation and the requests that are being made by Senator Kennedy and his staffers.

George L. Cary
Legislative Counsel

APPROVED:

Director of Central Intelligence

Date

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FORM NO. 241
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REPLACES FORM 36-8
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